## Message Text

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PAGE 01 TOKYO 00427 120625Z ACTION HEW-06

INFO OCT-01 EA-09 ISO-00 OES-06 AGRE-00 IO-13 AID-05 MED-03

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**UNCLAS TOKYO 0427** 

DEPT PASS FDA

E.O. 11652: N/A

TAGS: TBIO, TPHY, JA

SUBJECT: POSSIBLE REVISION OF ACCEPTABLE LEVEL OF INGESTION STANDARD FOR DIBUTYL HYDROXY TOLUENE (BHT).

1. JANUARY 12 EDITION OF JAPAN TIMES CARRIED A STORY REPORTING RECENT EFFORTS MADE BY A GROUP OF JAPANESE SCIENTISTS TO HAVE THE MINISTRY OF HEALTH AND WELFARE REVISE THE STANDARD FOR ACCEPTABLE LEVELS OF INGESTION FOR BHT. THE PRESENT ACCEPTABLE STANDARD IS SET AT 0.5 MG PER KILOGRAM OF BODY WEIGHT PER DAY. THIS STANDARD IS IN AGREEMENT WITH WORLD HEALTH ORGANIZATION (WHO) STANDARDS. HOWEVER, THE SCIENTISTS HAVE CLAIMED THAT THE WHO AND THE FAO COMMITTED ERRORS IN DETERMING THE SAFETY LEVEL AND SET THE STANDARD AT A HIGHER LEVEL THAN CORRECT. THEY ALSO CLAIM THAT THERE IS EVIDENCE TO INDICATE THAT THE LEVEL ESTABLISHED FOR BHT WAS ACTUALLY THE LEVEL SET FOR A SIMILAR BUT LESS TOXIC CHEMICAL, DIBUTYL HYDROXY ANISOLE (BHA). PRESUMABLY THE BHA STANDARD WAS ASSIGNED TO BHT DUE TO ADMINISTRATIVE ERROR.

2. THE SCIENTISTS, INCLUDING A LECTURER AT TOKYO UNIV.,
HAVE CLAIMED THAT THE TESTS USED TO ESTABLISH TOXICITY
OF BHT WERE DONE IN A CARELESS AND ERROR-RIDDEN MANNER AND
THAT THE MAXIMUM DAILY ALLOLANCE SHOULD BE MUCH LOWER THAN
THE PRESENT STANDARD. THEY FURTHER CLAIM THAT THE ORIGINAL
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TESTS, DONE BY DR. W.D. BROWN, OF AUSTRALIA, WERE OF TOO SHORT A DURATION TO ALLOW ADEQUATE DETERMINATION OF LONG TERM TOXICITY. THE MINISTRY OF HEALTH AND WELFARE HAS CITED A 1973 USFDA STUDY OF SAFETY STANDARDS FOR BHT AS INDICATION THAT THE OFFICIALLY ACCEPTED LEVEL IS SAFE.

3. FDA MAY RECEIVE INQUIRIES FROM JAPANESE SOURCES AS A RESULT

OF THIS CONTROVERSY. IF FDA HAS ANY MATERIAL RELEVANT TO THIS MATTER EMBASSY WOULD LIKE TO PROVIDE IT TO THE MHW. IN ADDITION, EMBASSY UNDERSTANDS THAT RESEARCH IS NOW BEING CONDUCTED IN U.S. INTO THE CANCER INHIBITING PROPERTIES OF ANTIOXIDANTS, SUCH AS BHT. IF DEPT. OR FDA CAN SUPPLY US WITH ANY DETAILS OR RESULTS FROM SUCH RESEARCH, WE WOULD LIKE TO PROVIDE THAT INFORMATION TO MHW. HODGSON

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## Message Attributes

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